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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,641	11/21/2000	Lisa J. Gerrard	P0645P4D2C3	9837

7590 09/08/2004

Genentech Inc
Attn: Timothy R Schwartz
1 DNA Way
South San Francisco, CA 94080-4990

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,641

Applicant(s)

GERRARD ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89 and 91-100 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 89 and 91-100 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed July 2, 2004.

Amendments were made to the claims. Specifically claim 90 was cancelled.

Claims 89 and 91-100 are pending and under consideration in the instant application.

Any rejection of record in the previous Office Action, mailed June 17, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Priority

Applicant suggests that priority should be granted for the instant application, concerning the limitation "wherein a suppressible termination codon is between or adjacent to the first and second genes," as of April 10, 1991. Applicant indicates that support for the limitation can be found at page 20, lines 15-21 and page 21, lines 19-22 and 32-36 in the Application filed April 10, 1991.

A review of the continuity of the instant application reveals that it is a continuation (CON) of 08/922,345, which is a CON of 08/463,587, which is a divisional (DIV) of 08/050,058, which is a 371 of PCT/US91/09133, which is a continuation-in-part (CIP) of 07/743,614, which is a CIP of 07/715,300, which is a CIP of 07/683,400, which is a CIP of 07/621,667. The Application filed April 10, 1991 (07/683,400) is a File-Wrapper Continuation of 07/621,667, thus the earlier Application (09/621,677) contains all of the information (specification,

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amendments, etc.) that represents Application 07/683,400. A review of 07/621,667 reveals no support (either original or as amended) for the limitation "wherein a suppressible termination codon is between or adjacent to the first and second genes." Indeed, pages 20 and 21 as referenced by Applicant as indicating support for the limitation, does not indicate such support, and it does not appear that any amendment was made at said locations concerning the aforementioned limitation. In view of an absence of clear support for the limitation "wherein a suppressible termination codon is between or adjacent to the first and second genes" prior to the filing of PCT/US91/09133, Applicant is only granted priority to December 3, 1991.

Information Disclosure Statement

The information disclosure statement filed April 10, 2003 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action. It is noted that references 88, 91, 212 and 217 have been lined through because these references have already been considered on the record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 89 and 91-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse (US Patent No, 5,770,434; as cited previously; see entire document) in view of Ladner (US

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5,223,409; as cited previously; see entire document). **This rejection is necessitated by amendment.**

Huse teaches the expression of random peptides on the surface of M13 filamentous bacteriophage by combining random oligonucleotides functionally linked both to gVIII coat protein and to expression elements in the form of a single vector (see for example column 10, lines 37-65). The purpose of the gVIII coat protein is to target the random peptide to the outer surface of the phage. The vector contains stop codons downstream of the random peptide, between the random peptide and the phage coat protein, and the stop codon can either be an amber, ochre or opal suppressible stop codon (see for example column 11, line 49 to column 12, line 16). This results in the expression of a fusion protein comprising a first polypeptide and a second polypeptide, wherein the second polypeptide is at least a portion of a filamentous bacteriophage coat protein, wherein a suppressible stop codon is located between the two polypeptides (see for example column 4, lines 16-32). Huse also anticipates host cells comprising these vectors (see for example column 4, lines 31-32).

Huse does not teach using *just* a portion of a phage coat protein, nor does Huse teach the use of the gIII coat protein to target the random peptide to the surface of the phage particle.

Ladner teaches a method of phage display, and the resulting products therein, using a number of different phage coat proteins. This includes the filamentous phage M13 coat proteins encoded by gene III and gene VIII (see for example column 51, lines 46-68), wherein Ladner teaches that either gIII or gVIII represents a highly preferred coat protein for the display of random peptides on the surface of the phage particle (see for example column 56, lines 63-66). The use of these coat proteins is attractive because the processing of the coat protein is well

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understood (see for example column 55, lines 37-53). It is additionally noted that Ladner teaches using portions of the phage coat proteins in the fusions (see for example column 109, lines 10-23). For example, teaches the construction of a fusion polypeptide that comprises the M13 gene III signal peptide sequence fused to bpti, further fused to a mature gVIII coat protein; in this fusion, both the gIII signal peptide (lacking the C-terminal portion of the coat protein) and the mature gVIII peptide (lacking the N-terminal signal sequence) represent portions of coat proteins; it is also noted that Ladner teaches using other well known signal peptides in conjunction with the C-terminal portion of the gVIII coat protein. Ladner teaches that making such fusion proteins using only portions of each coat protein is desirable because of the controversy surrounding the mechanism by which the coat proteins are directed for surface expression, and that the substitution will obviate any problems with such targeting (see for example column 108, line 42 to column 109, line 23). Finally, Ladner points to teachings where an antibody fragment was fused to coat protein III of a bacteriophage.

It would have been obvious to combine the teachings of Huse and Ladner because both teachings regard the display of random peptides of the surface of a phage particle, using the coat proteins of the M13 filamentous bacteriophage. The ordinary skilled artisan would have been motivated to combine the teachings of Huse and Ladner in order to use coat proteins that were well understood in terms of their processing (as taught by Ladner), and could therefore be readily manipulated for the purpose of displaying random peptides on the surface of a phage particle, as taught by Huse. Motivation for using just portions of the respective coat proteins is taught by Ladner, who advocates doing so in order to ensure the proper targeting of the fusion protein for surface expression. Absent evidence to the contrary, and given the teachings in the prior art at

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the time of the invention, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the invention as taught by Huse and Ladner.

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed July 2, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal: It is argued that the claims as amended read on the use of only a *portion* (original emphasis) of a coat protein when constructing the claimed gene fusion. The contention is made that Huse does not teach such a gene construct, and that Ladner does not cure the deficiency of Huse.

The arguments are not convincing because, as set forth in the rejection above, Ladner does indeed teach the use of only a *portion* (original emphasis) of a coat protein in their gene fusions. This is evident from the use of both the M13 gIII signal peptide (absent the remainder of the coat protein) and the mature gVIII coat protein (absent the native signal peptide sequence) in the gene fusions taught by Ladner. Thus, the argument that this teaching is not present in the applied references does not appear to be valid.

It is further noted that no evidence or argument is presented concerning the obviousness, motivation or expectation of success for combining the teachings of Huse and Ladner. As such, it can only be presumed that the obviousness, motivation and expectation of success provided by the Office satisfied the requirement of *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 89 and 91-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7 and 14 of U.S. Patent No. 6,040,136 (henceforth the '136 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious in view of claims 12 and 14 of the '136 patent. **This rejection is maintained for reasons set forth in the previous Office Action.**

Claims 89 and 91-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-34 of U.S. Patent No. 5,750,373 (henceforth the '373 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are genus claims that are anticipated by the specific claims of the '373 patent. **This rejection is maintained for reasons set forth in the previous Office Action.**

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Allowable Subject Matter

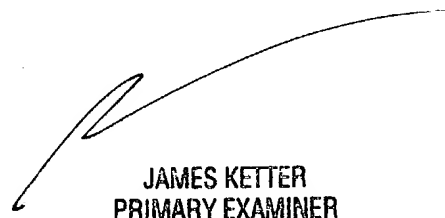
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER